

EXHIBIT 10

From: Yale, Mark [ETHUS]
Sent: Fri, 09 May 2008 08:53:27 GMT
To: Meek, Jonathan [ETHUS] <JMeek1@ETHUS.JNJ.com>
Subject: Re: DRAFT FDA Response on PROLIFT +M for input

It is the fine balance between dumbing down the information so patient gets actual benefit from not stepping over boundary where the FDA takes exception. The word "specifically" is where we can get caught by FDA.

Mark

Sent via Blackberry
Mark C Yale
Director WW Risk Mgt
ETHICON
Phone 908.218.2326
Mobile 908.405.7287

----- Original Message -----

From: Meek, Jonathan [ETHUS]
To: Yale, Mark [ETHUS]
Sent: Thu May 08 15:02:53 2008
Subject: RE: DRAFT FDA Response on PROLIFT +M for input

The issue for the patient is that something called 'synthetic material' is pretty limited in its value or description. Meshes are specifically design for tissue reinforcement which is a fact. The key point is that the synthetic material is really a specifically designed tissue reinforcement...synthetic material

Jonathan Meek
Worldwide Marketing Director
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(+1) Office: 908 541-3863 | Mobile: 908 938 7590 | jmeek1@ethus.jnj.com

-----Original Message-----

From: Yale, Mark [ETHUS]
Sent: Thursday, May 08, 2008 2:22 PM
To: Paine, Jennifer M. [ETHUS]; Meek, Jonathan [ETHUS]; Lisa, Bryan [ETHUS]; Robinson, David [ETHUS]; Guidry, Cyrus [ETHUS]; St. Hilaire, Price [ETHUS]; Zaddem, Vincenza [ETHUS]
Cc: Mauge, Christophe [ETHUS]; Mahar, Kevin [ETHUS]; Gadot, Harel [ETHUS]; Jacobs, Ed M [ETHUS]
Subject: RE: DRAFT FDA Response on PROLIFT +M for input

Jennifer,

I'll just weigh in on the "specifically designed synthetic mesh". This mesh was not "specifically designed" for Prolift application, we pulled a mesh out of our existing bag of tricks. This statement is unsupportable form a design history standpoint.

Mark C. Yale



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-----Original Message-----

From: Paine, Jennifer M. [ETHUS]

Sent: Thursday, May 08, 2008 2:18 PM

To: Meek, Jonathan [ETHUS]; Lisa, Bryan [ETHUS]; Robinson, David [ETHUS]; Guidry, Cyrus [ETHUS]; St. Hilaire, Price [ETHUS]; Zaddem, Vincenza [ETHUS]

Cc: Mauge, Christophe [ETHUS]; Mahar, Kevin [ETHUS]; Gadot, Harel [ETHUS]; Yale, Mark [ETHUS]; Jacobs, Ed M [ETHUS]

Subject: RE: DRAFT FDA Response on PROLIFT +M for input

Hi Jonathan,

Thanks for the input - I like the change to "treatment" versus "intervention" and agree it is more likely to be understood by the patient.

With regard to the specifically designed synthetic material... I'm still on the fence on this one. If you look at Gynemesh PS, and doesn't differ substantially from PROLENE SM, so there are going to be general cases where "specifically designed synthetic mesh" wouldn't be entirely accurate. In fact, some docs use natural materials (collagen?) rather than synthetics, so not even sure we should be as specific as to say synthetic?

Apologies also to all the folks getting copied a million times - wanted you to see the response and have an opportunity to provide input since time is VERY short to get this out to FDA tomorrow.

Let me how strongly you guys feel about rewording the special synthetic mesh stuff and we might be best served by a brief telecon or meeting later today to hash it out. Thx,

Jennifer Paine

Director, Regulatory Affairs

Ethicon, Inc.

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-----Original Message-----

From: Meek, Jonathan [ETHUS]

Sent: Thursday, May 08, 2008 2:08 PM

To: Paine, Jennifer M. [ETHUS]; Lisa, Bryan [ETHUS]; Robinson, David [ETHUS]; Guidry, Cyrus [ETHUS]; St. Hilaire, Price [ETHUS]; Zaddem, Vincenza [ETHUS]

Cc: Mauge, Christophe [ETHUS]; Mahar, Kevin [ETHUS]; Gadot, Harel [ETHUS]; Yale, Mark [ETHUS]; Jacobs, Ed M [ETHUS]

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I think it looks pretty thorough.

A couple of minor thoughts: The patient brochure uses the word 'intervention' (Exposure may require intervention such as vaginal medication or removal of the exposed mesh) which may not resonate with the patient. It may be more patient friendly to read Exposure may require treatment such as... or even Exposure may require care such as...???

To Prices' point, the intent to use the word 'special' as it appears in 'special synthetic material' was to be conducive with specific or specific to a particular need. I would like to see the word replaced with another adjective that described that the synthetic material was specifically design to reinforce the patients tissue. Can I suggest it reads "specifically designed synthetic material"

Nice work Jennifer and Bryan, thanks for your support

Jonathan Meek

Worldwide Marketing Director

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-----Original Message-----

From: Paine, Jennifer M. [ETHUS]

Sent: Wednesday, May 07, 2008 9:40 PM

To: Lisa, Bryan [ETHUS]; Robinson, David [ETHUS]; Guidry, Cyrus [ETHUS]; Meek, Jonathan [ETHUS]; St. Hilaire, Price [ETHUS]; Zaddem, Vincenza [ETHUS]

Cc: Mauge, Christophe [ETHUS]; Mahar, Kevin [ETHUS]; Gadot, Harel [ETHUS]; Yale, Mark [ETHUS]; Jacobs, Ed M [ETHUS]

Subject: DRAFT FDA Response on PROLIFT +M for input

Importance: High

Hi all,

Please review the draft attached - still needs refinement but is a good place to start. Since many of our marketing partners were unable to participate in the call yesterday, I would ask that you in particular provide any input you have on the proposed strategy for each issue. This has to be finalized by Friday morning to send out by 4 pm on Friday. Thanks!

<< File: PROLIFT+M May Resp.doc >>

Jennifer Paine

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